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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,060	02/17/2004	Spyridon Artavanis-Tsakonas	7326-131	8375

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EXAMINER	
DUTT, ADITI	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,060	ARTAVANIS-TSAKONAS ET AL.	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,19,21,23,29,30,32-34 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,19,21,23,29,30,32-34 and 46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 19 and 21, drawn to pharmaceutical composition comprising a Notch protein and Notch binding proteins, classified in class 530, subclass 350+.

II. Claim 23, 29, 30, drawn to pharmaceutical compositions comprising nucleic acids encoding Notch protein and Notch binding proteins, classified in class 435, subclass 69.1+.

III. Claims 32 and 33, drawn to pharmaceutical composition comprising antibodies to Notch protein, classified in class 530, subclass 387.1+.

IV. Claims 34, drawn to methods of treatment of disease using antagonist to Notch proteins, class 530, subclass 387.1.

V. Claims 46, drawn to methods of treatment of disease using agonist to Notch proteins, class 530, subclass 387.1.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons:

1. The protein of Invention I is related to the nucleic acids of Invention II by virtue of encoding same product. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecules and proteins are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). The DNA claims do not overlap the scope of the protein claims and vice versa as evidenced by the distinct structures and functions of the claimed inventions. A DNA's structure is comprised of linear, contiguous nucleotides while a protein's structure comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the DNA's function is to encode a protein while a protein's function is variable. The nucleic acid of Group II can be used to make a hybridization probe as well as in the production of the protein of interest. The protein of Group I can be used other than to make the antibody as in Group III, such as used as a probe, or used therapeutically. Additionally, the DNA and polypeptides are not obvious variants of each other based on the distinct structures and functions of each as noted above. Thus, by virtue of the different structures and functions of the inventions of Groups I and II, these inventions are distinct.

2. The polypeptide of Invention I is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although

the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

Inventions I and III are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP 806.05(j). In the instant case, the protein claims of Group I do not overlap the scope of the antibody claims of Group III and vice versa as evidenced by the distinct structures and functions of the claimed inventions. While both protein and antibodies are structurally related by virtue of their contiguous sequence of amino acids, they are distinct structures based on their three-dimensional structures wherein proteins fold into a variety of structures and antibodies maintain a specific, Y-shape. Proteins are functionally distinct from antibodies because antibodies merely recognize a cognate peptide fragment of said polypeptides that affect a specific binding to Notch protein as in the instant case. Additionally, the protein and antibodies are not obvious variants of each other based on the distinct structures and functions of each as noted above and hence each have acquired a separate status in the art as shown by their different classification.

3. Groups I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the process such as treatment of disease as claimed in Group IV cannot be practiced with Notch proteins of Invention I, because the treatment method uses antagonist to Notch protein.

4. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Notch protein of invention I could function as a Notch agonist used for treatment claimed in invention V. Notch protein could also be used for making antibodies and in Western assays.

5. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions such as DNA of Group II and antibody of Group III, not only are structurally and functionally different, but also have different effects. For

example, DNA can be used in gene therapy and the antibody can be used to identify the protein or can be used in treatment.

6. Inventions II, IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case nucleic acid of Group II can be used for treatment of Group IV and V utilizing gene therapy protocol. Additionally, the DNA can also be used for gene expression studies by in-situ-hybridization methods besides getting translated to Notch protein.

7. Inventions III, IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Notch protein antibody could be used as antagonist in the treatment claim of invention IV, although processes in the present claims do not require the antibodies. Antibodies can also be used for other purposes like binding assays.

8. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions IV and V having treatment claims using antagonist and agonist to Notch protein respectively, are mutually exclusive processes, each having different functions eliciting opposite effect from the other. Therefore, a search and examination of the two methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and the search required for each group is unique, and because each protein or nucleic acid requires a completely separate search, as well as by their different classifications, divergent subject matter and different search requirements as explained earlier, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Groups I through IV. Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Secondary Election/Restriction

10. Restriction to one of the following inventions is required under 35 U.S.C. 121:

If Applicant selects one of the inventive Groups I and II (above, page 2), one protein/DNA from each group below must also be selected to be considered responsive for examination:

a) Notch

b) Delta

c) Serrate

11. Each of the above protein/DNA molecules represents a patentably distinct invention. Each of the above has a distinct DNA moiety, thereby translating to different polypeptides having different functions. Thus, they are independent and distinct entities that require completely different search.

Note: This is a Restriction requirement, not an Election of species. This election applies regardless of whether elected claims read on protein or DNA.

Notice of Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037. The examiner can normally be reached on M-F 9.00 a.m. to 5.00 p.m. (Eastern standard time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER